

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 655954**
Issued To: **VITREQ B.V.**
Seggelant-Noord 2
Vierpolders
3237 MG
Netherlands

In respect of:

Those aspects of manufacture related to securing and maintaining sterility of vitrectomy sutureless lenses.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **11 July 2016**

Date: **11 July 2016**

Expiry Date: **16 February 2021**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

Rose GmbH Medizin- und
Sterilisiertechnik
Gottbillstr. 25-30
Trier
54294
Germany

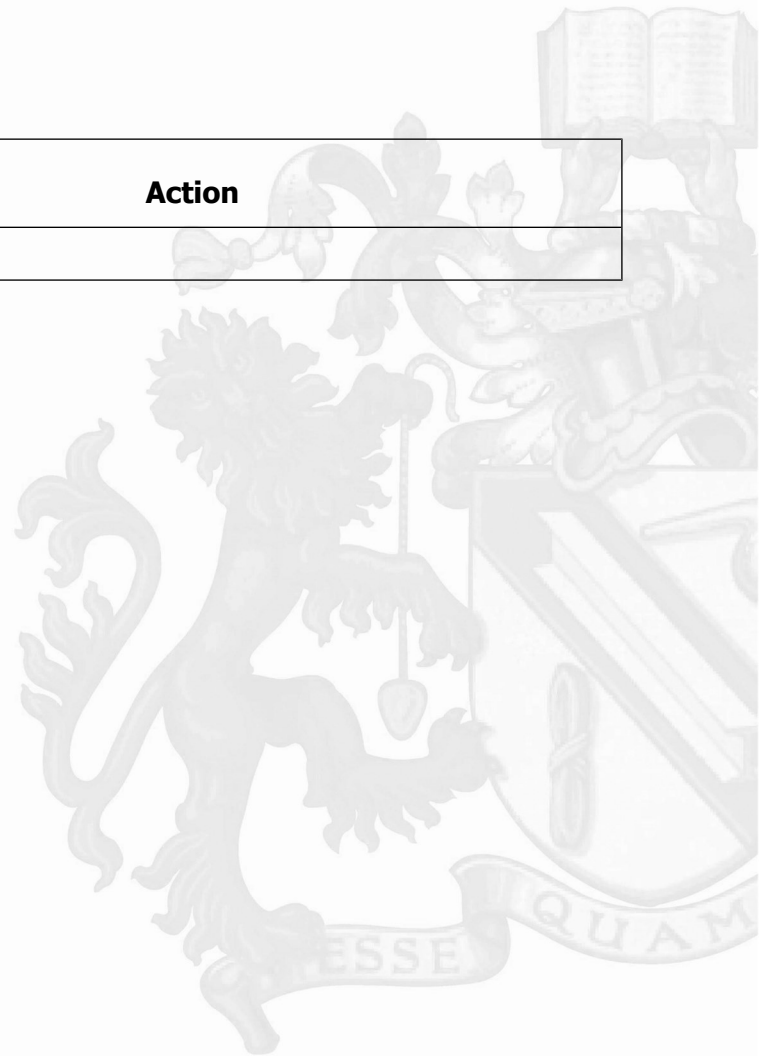
ETO Sterilization

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 655954**
 Date: **11 July 2016**
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 Seggelant-Noord 2
 Vierpolders
 3237 MG
 Netherlands**

Date	Reference Number	Action
11 July 2016	8555561	First issue.



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